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Notice of Reasons for Refusal

Application No.: Japanese Patent Application No. 291584/2003

Date: September 7, 2009

Examiner: Toshiyasu KIMURA 8910 4H00

Applicant's representative: Mr. Shuichi Takahashi (one other)

Applied provision: Article 29(1), Article 29(2), Article 29-2, Article 36 and Article 37 of the Patent Law

This patent application has been rejected for the following reasons. If you have opinions, you are requested to file a written argument within 60 days from the mailing date of this notice.

Reasons

1. Since the inventions relating to the following claims of this application are the inventions described in the following distributed publications in Japan or in a foreign country or available to public on electrical line before the filing of the present application, the inventions cannot be patented according to the provision of Article 29(1)(iii) of the Patent Law.

2. The present invention cannot be patented according to the provisions of Article 29(2) of the Patent Law, because the invention claimed in the following claims could have been made with ease before the filing of the present application by those having ordinary skill in the art pertaining to the technical field of the present invention, based on the inventions described in the following publications distributed in Japan or in a foreign country or available to public on electrical line before filing of the present application.

3. The present invention cannot be patented according to the provisions of Article 29-2 of the Patent Law, because the invention claimed in the following claims of this patent application is identical with an invention disclosed in the description, scope of claims or drawings originally attached to the written application of the following application for a patent which has been filed prior to the date of filing of this patent application and published after the filing of this patent application in the patent gazette, and the inventor of this patent application is not the same as the person who made

the above-mentioned invention relating to the patent application filed prior to the date of filing of this patent application and, at the time of the filing of this patent application, the applicant of this patent application and the applicant of the above-mentioned patent application are not the same person.

4. The Claims and Detailed Description of the Invention of this application do not satisfy the requirements according to the provision of Articles 36(4)(iv) and (6)(i)-(iii) of the Patent Law on the points mentioned below.

5. This application does not satisfy the requirements according to the provisions of Article 37 on the points mentioned below.

Note (Cited references are shown in the List of Cited References.)

[Reasons 1 and 2]

Referring to the General Formula (I) of the present application, the "3-chloro-4-(4-hydroxyphenyl)-1-naphthalenecarboxamide (compound A)" described on page 46 in Cited Document 1 falls in the scope of compounds of the invention of the present application because the ring A is a 6-membered ring (benzene ring), the ring B is a 6-membered ring (benzene ring), the ring C is a benzene ring (a benzene ring substituted by a chlorine atom), each of X1 and X2 is a carbon atom, W (in case where the ring A is a benzene ring) is a group represented by the formula CRa (wherein Ra represents a bond), each of R2 to R5 in Y11 and Y21 is a hydrogen atom, and R1 is an electrophilic group (-CHO).

While the compound 420 mentioned on page 65 in Cited Document 2 is a compound coming under the statement "except for cases such as 1) where W is a nitrogen atom, and ring B is an optionally substituted piperazine ring, ..." in the claim 1 of the present application, it is described in the claim 1 in Cited Document 2 that "B is 4-piperidine, 4-tetrahydro-1,2,3,6-pyridine, 4-piperazine or the like"; therefore, the compound described in Cited Document 2 is not limited to cases where B is a piperazine ring, and the compounds of the invention of the present application are identified as the compound described in Cited Document 2.

Although the compound 178 mentioned on page 307 in Cited Document 3, the "1-(4-cyano-1-naphthyl)-3-methylpiperazine"

mentioned on the 19th line on page 112 in Cited Document 4, the compound 37 mentioned on page 59 in Cited Document 5, the compound mentioned in Example 7 on page 64 in Cited Document 6, and the compounds mentioned in the 3rd to 5th lines on page 34 in Cited Document 7 are excluded as a disclaimer (excluding claim) from the General Formula of the invention of the present application, the generic concept thereof overlap the invention of the present application.

Referring to the General Formula (I) of the application of the present application, the "N-(4,5-dinitronaphthyl)piperidine" mentioned in the lower right column on page 48 in Cited Document 8 falls in the scope of compounds of the present application because the ring A is a 6-membered ring (a benzene ring substituted by a nitro group), the ring B is a 6-membered ring (piperidine ring), the ring C is a benzene ring, each of X1 and X2 is a carbon atom, W is a nitrogen atom, each of R2 to R5 in Y11 and Y21 is a hydrogen atom, and R1 is an electrophilic group (nitro group).

Cited Document 9 describes the use of a series of compounds different from the invention of the present application only in that the ring A according to the invention is not present, as anti-androgen agents for the prevention/treatment of prostatic cancer.

For these reasons, the inventions in the claims 1 to 26 of the present application are substantially described in Cited Documents 1 to 8, and could easily have been made by a person skilled in the art on the basis of the inventions described in Cited Documents 1 to 9.

[Reason 3]

The compounds 61, 71 and the like mentioned in the paragraphs 0185 to 0185 in an earlier application A, the compounds mentioned in Examples 36 and 37 in an earlier application B, and the intermediates 1 to 5 mentioned in the paragraphs 0071 to 0075 in an earlier application C all fall in the scope of the compounds claimed in the claims 1 to 15 of the present application.

For this reason, the inventions in the claims 1 to 15 of the present application are identified as inventions described in the original specifications for the earlier applications A to C.

[Reason 4]

(a)

Regarding the definitions for General Formulas (I), (Ia), (IIa), (IIb), (III) and (I') given in the claims 1 to 15 of the present application, there is a statement to exclude some compounds by expressions such as "except for ...". However, because a statement in the scope of claims using such an expression falls in 'cases where the scope of the invention is ambiguous due to the presence of a negative expression ("excluding something", "not something" and the like)', and does not correspond to a case where "a shared chemical structure is present in common, i.e., all options share an important chemical structural factor in common" as a result of the exclusion of some compounds by such a negative expression, the definitions do not correspond to "definitions that allow the clear understanding of one invention" in "cases where the description in an alternative form such as the Markush form concerns a chemical substance"; therefore, the inventions in the claims 1 to 15 of the present application and dependent claims thereof are not inventions that are clearly defined for which a patent is sought. Additionally, because the "prophylactic/therapeutic method" claimed in the claim 22 of the present application is not an industrially applicable invention, the technical implication is unclear. Thus, the statements in the claims 1 to 26 of the present application do not comply with the requirements under Patent Law Section 36 (6) (ii).

As for the definitions for the compounds given in the claims 1 to 15 of the present application, the statements fall in "cases where the conciseness of the description of a claim is considerably diminished due to a large number of options in a description in an alternative form such as an invention for a chemical substance described in the Markush form", and the statement for each claim is not recognized as being concise; therefore, the definitions do not comply with the requirements under Patent Law Section 36 (6) (iii).

For this reason, the statements in the claims 1 to 26 of the present application do not comply with the requirements under Patent Law Section 36 (6) (ii) and (iii).

(b)

Regarding the definitions for General Formulas (I), (Ia), (IIa), (IIb), (III) and (I') given in the claims 1 to 15 of

the present application, the invention-specifying matters therein, such as "5- to 8-membered ring", "4- to 10-membered ring", "optionally substituted", and "electrophilic group", are unclear for the definition of a chemical structure, and the definitions are ambiguous for the description of a chemical substance invention in that the coverage of specific substituents, the number of atoms in the main chain, and the structure of the main chain as speculated from these statements are not clear.

While a high-court judgment tells, 'Generally, in a use invention for a medicine, it is difficult to predict the utility thereof from the name or chemical structure of the substance, and even when the effective dose, method of administration, and matters for preparation making are described to some extent in the detailed description of the invention, the description alone does not suffice to enable a person skilled in the art to know whether or not the medicine is actually useful in the use, and to realize that the problems to be solved by the invention can be solved; therefore, the utility of the use should be evidenced by further providing pharmacological data or matters that can be deemed equivalent thereto. Conversely, if the statements in the scope of claims deviate from the detailed description of the invention, the statements in the scope of claims are judged to be in violation of what are called the support requirements under Patent Law Section 36 (5) (i)' (reference judgement: Heisei 17 (Gyo Ke) 10818), the extremely large number of compounds included in the options of the invention of the present application, except for the particular chemical substances verified specifically in the specification, cannot be said to be obvious to a person skilled in the art to the extent deemed as described; therefore, the teachings disclosed in the detailed description of the invention cannot be broadened or generalized to the extent of the scope of the inventions of the present application, and even a person skilled in the art cannot embody the inventions concerning all options of the compounds described in the scope of claims of the present application, without doing excess trial-and-error work.

For this reason, the claims 1 to 26 of the present application cannot be said to clearly define an invention for which a patent is sought; therefore, the claims do not comply with the requirements under Patent Law Section 36 (6) (ii), and seem to intend to claim a patent even in a scope not substantially described as an invention in the detailed

description of the invention in the specification for the present application, so that the claims do not comply with the requirements under Patent Law Section 36 (6) (i). Additionally, because the detailed description of the invention in the specification for the present application does not disclose the inventions in the claims 1 to 26 of the present application in a manner sufficiently clear and complete for the inventions to be carried out by a person skilled in the art, in view of the provisions in the Section 24 bis of Regulation under Patent Law (Ministerial Ordinance requirement) 'Statements of the detailed description of the invention which are to be in accordance with an ordinance of the Ministry of International Trade and Industry under Section 36(4) shall state the problem to be solved by the invention and its solution, or other matters necessary for a skilled person in the art to understand the technical significance of the invention.'; therefore, the detailed description does not comply with the requirements under Patent Law Section 36 (4) (i).

[Reason 5]

Because the invention in the claim 1 of the present application is an invention described in Cited Documents 1 and 8, as stated above, and was therefore publicly known already before the filing of the present application, the problems to be solved thereby have already been solved, and the indispensable constituent features of the invention for which a patent is sought no longer convey novelty.

Hence, in determining whether or not the inventions in the claims 1 to 26 of the present application mutually "have the same problems to be solved", "a problem to be solved" means "a technical problem to be solved by the invention that has been unresolved until the filing of the application", and "have the same problems to be solved" means "a case where a specified invention and a related invention have a problem to be solved in common". Because the "problems to be solved" by the inventions in the claims 1 and 4 of the present application had already been solved at the time of the filing of the present application, such problems are no longer present, and the mutual relationship among the inventions in the claims 1 to 26 of the present application does not fall in "a case where the inventions have the same problems to be solved", so that the claims 1 to 26 do not comply with the requirements under Patent Law Section 37 (i).

In determining whether or not the inventions in the claims 1 to 26 of the present application mutually "have the same substantial part of the indispensable constituent features", "have the same substantial part of the indispensable constituent features" means a case where "the new constituent features corresponding to problems to be solved by the specified invention" and the new constituent features corresponding to problems to be solved by the related invention are the same"; the invention in the claim 1 of the present application lacks novelty as stated above; therefore, there are no "new constituent features corresponding to problems to be solved", and the mutual relationship among the inventions in the claims 1 to 26 of the present application does not fall in "a case where the inventions have the same substantial part of the indispensable constituent features"; therefore, the claims 1 to 26 do not comply with the requirements under Patent Law Section 37 (ii).

Even if any one of the inventions in the claims 1 to 26 of the present application is handled as a specified invention, the requirements under the items in Patent Law Section 37 are not met in relation to the inventions in the other claims.

For this reason, the inventions in the claims in the scope of claims of the present application do not comply with the requirements under the items in Patent Law Section 37; therefore, a patent application cannot be filed with a single request for patents for these inventions.

List of Cited References

1. JP-A-2000-504335
2. WO 00/41697
3. WO 02/14271
4. WO 02/50067
5. WO 01/02392
6. JP-A-2001-516719
7. JP-A-08-504410
8. J. Org. Chem., Vol.41, No.1, 1976, p44-48
9. JP-A-2002-088073
- A. Japanese Patent Application No. 2003-520749 (JP-A-2005-502656)
- B. Japanese Patent Application No. 2001-146270 (JP-A-2005-022972)
- C. Japanese Patent Application No. 2003-503591 (JP-A-2004-536080)

(Note) Due to restrictions by law, contract, etc., a part or the entirety of the indicated non-patent documents may not be

mailed.

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Record of search of prior art references

- Field searched DB name CAplus(STN)
- Prior art references JP-A-2003-252854
- This record of search of prior art references does not constitute the grounds of refusal.